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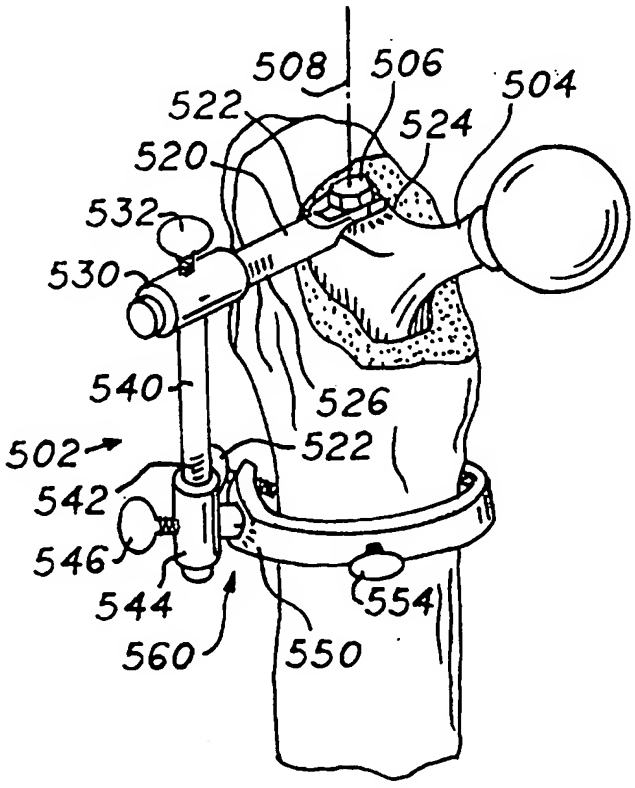
(54) Title: METHOD AND APPARATUS FOR POSITIONING A PROSTHETIC ELEMENT RELATIVE TO A BONE TO ACHIEVE A DESIRED ORIENTATION

(57) Abstract

Apparatus and method are disclosed for maintaining the proper positioning of an implant (310, 504) within a prepared bone cavity (312) during cement injection and curing. First stabilization means (340, 480), implantable within the bone cavity, minimize lateral movement of the implant distal end, while second stabilization means (330, 334, 406, 404), physically separate from the first stabilization means (340, 480), minimize both the lateral movement of the implant proximal end and the rotational movement of the implant overall. In the preferred embodiment, the second stabilization means (330, 334) includes an aperture cap (334) removable securable to the end of a prepared bone. This cap (334), preferably further includes first and second ports (322, 336) associated, respectively, with cement injection and cement over-pressurization. In an alternative embodiment, the second stabilization means (406, 404) includes a manually operated mechanism enabling (404) the implant (504) to be temporarily, yet rigidly, secured thereto in accordance with a desired orientation, preferably affording adjustments along multiple degrees of freedom prior to the rigid securement thereof.



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METHOD AND APPARATUS FOR POSITIONING A PROSTHETIC ELEMENT RELATIVE TO A BONE TO ACHIEVE A DESIRED ORIENTATION

Field of the Invention

This invention relates generally to arthroplasty and, more particularly to devices and techniques for positioning a prosthesis prior to fixation through the injection of a bonding agent.

Background of the Invention

In current human joint repair situations, it is common practice to prepare host bone stock to receive an implant then, if satisfied with the physical correspondence, apply cement to the host, install the prosthesis, and stabilize the arrangement until curing. This approach has several disadvantages. Foremost among them arises from the unpredictable process of ensuring that, although the prosthesis may have been ideally placed prior to cementation, once the cement is applied, orientation may shift, resulting in a final configuration which is less than optimal.

A few approaches have been attempted to assist in making the positioning of the final implant more predictable. As discussed further in the detailed description herein, one such approach utilizes a centralizing plug inserted distally within the medullary canal, and from which there extends a rod upon which a final implant including a corresponding central bore may be monorailed. The plug and rod are positioned in conjunction with a trial which also includes a central bore, which is then removed, the intramedullary cavity filled with cement and the final implant slid over the rod, displacing the

cement as it is pushed down into position. Although this technique may assist in maintaining a side-to-side orientation prior to cementation, it does not address the simultaneous need for up-and-down and/or rotational stabilization. Additionally, as with current techniques, cement is applied to the host prior to the introduction of the final implant, leaving open the possibility that the final implant may be held in a position different from that associated with the trial, and may therefore result in an unacceptable misplacement as the cement cures.

Other approaches do reverse this order, and install the final implant prior to the injection of cement. The known approaches, however, utilize a highly specialized prosthetic device including centralizing protrusions and internal channels through which the cement is introduced. That is, in these systems, the prosthesis itself is used as the cement injector. Due to their requirement for a highly specialized final prosthetic element, such systems are incompatible with currently available implant devices, and therefore raise costs while reducing the options of the practitioner. In addition, they do not adequately address the need for simultaneously stabilizing multiple degrees of freedom prior and during cementation. As a further disadvantage, the systems which use the prosthesis as the cement injector tend to use the cement as a grout between the outer surface of the implant and the inner surface of the receiving cavity. It has been shown, however, that the changes of success are improved through the creation of a thicker cement "mantle," as opposed to a thin grout-type layer. The need remains, then, for a system whereby the prosthesis may be stabilized relative to multiple degrees

of freedom prior to cementation, and, ideally, remain compatible with existing prosthetic components while forming a strong and stable bond to the host.

Summary of the Invention

The present invention resides in apparatus and methods for maintaining the proper positioning of a prosthetic implant having proximal and distal ends within a prepared bone cavity during cement injection and curing. In contrast to prior-art systems the invention provides first stabilization means, implantable within the bone cavity, for minimizing lateral movement of the distal end of the implant, and second stabilization means, physically separate from the means for minimizing lateral movement of the distal end of the implant, for minimizing both the lateral movement of the proximal end of the implant and the rotational movement of the implant overall. In the preferred embodiment, the second stabilization means includes an apertured cap removably securable to the end of a bone having the prepared cavity through which the implant is inserted and held in place. This cap, which may either be entirely rigid or include a pliable membrane in the vicinity of the aperture, preferably further includes a first port associated with cement injection and a second port associated with cement over-pressurization. In an alternative embodiment, the second stabilization means includes a manually operated mechanism enabling the implant to be temporarily yet rigidly secured thereto in accordance with a desired orientation, preferably affording adjustments along multiple degrees of freedom prior to the rigid securement thereof.

Brief Description of the Drawings

FIGURE 1A illustrates, in skeletal form, the first step of a prior-art implantation sequence involving host bed preparation;

FIGURE 1B depicts an intermediate step in the prior-art sequence wherein the cavity prepared according to Figure 1A is filled with cement;

FIGURE 1C illustrates the final phase of this prior-art sequence wherein a femoral prosthesis is inserted into the injected cement prior to hardening;

FIGURE 2A illustrates a prior-art improvement over the sequence shown in Figures 1A through 1C, wherein a distal plug is used for distal centering of the implant;

FIGURE 2B illustrates yet another prior-art improvement over the approach of Figure 2A wherein a vertically oriented rod is attached to the distal plug over which an implant may be slid after cement injection to further inhibit movement during curing;

FIGURE 3 is an arrangement according to this invention showing the use of a proximal cap which may be used either with a specially prepared prosthetic device or commercially available unit;

FIGURE 4 illustrates two independently usable alternative embodiments according to the invention, including a multiple degree-of-freedom proximal retainment structure and a distal plug including leaf springs; and

FIGURE 5 is a drawing which shows, from an oblique perspective, an alternative embodiment of the invention which clamps around the femur below the area of resection, and attaches to an elongated fastener oriented generally lengthwise with respect to the implant.

Detailed Description of the Preferred Embodiments

Figure 1 of U.S. Patent 5,340,362 shows an existing, prior-art procedure for inserting and cementing a prosthesis into a bone cavity, and this figure has been reproduced herein. In accordance with this technique, the canal is reamed or broached as shown in Figure 1A, and a trial is typically inserted thereinto to ensure that the final prosthetic component will be properly received. After this trialing, cement is injected into the excavated area as shown in Figure 1B, and the prosthesis is inserted as shown in Figure 1C, and left in position while the cement hardens. As discussed in the background of the instant invention, the technique just described is deficient in that, although the prosthesis may be optimally oriented during the trial procedure, the position of the actual implant may shift upon insertion into the cemented host or thereafter, resulting in a misaligned final fixation.

Various improvements also exist in the prior art to minimize such adjustment problems. At the very least, as shown in Figure 6 of U.S. Patent 4,994,085, reproduced herein as Figure 2A, a distal centralizer 16 is inserted beforehand into the intramedullary cavity 13 to which the distal tip 17a of the implant 17 engages at point 16a. This, at least, stabilizes the relative position of the distal tip 17a, resulting in a narrower range of angles (A to B) through which the implant 17 may move within the cement-filled cavity prior to final curing. The teachings of this reference further improve upon post-cementation stabilization by incorporating a stabilizing rod 4 into the distal plug 6 over which a specially designed implant 2

having a centralized hole 4 is slidably installed, as shown in Figure 2B herein (Figure 4 of the issued patent). Assuming the various connections between rod 5, plug 6 and the inner walls of the intermedullary canal are relatively rigid, and the various tolerances involved are substantially tight, movement of the implant 2 is further restricted until the cement finally cures.

Another approach taken according to the prior art involves the injection of cement after positioning of a specially designed implant into a prepared cavity. The '362 patent referenced above is directed toward such an approach. As with other arrangements of type, the final implant includes a cement canal along its longitudinal axis. A bone-cement injector is threaded onto the proximal portion of this cement canal, causing the cement to subsequently travel down and through the implant, eventually exiting through openings in and around its distal tip. A restrictor plug halts downward cement travel, thus initiating an upward, retrograde filling of the void in between the prosthesis and the cancellous bone wall. In addition to a single distal aperture through which the injected cement is introduced, side ports may also be included, as shown in U.S. Patent 4,274,163 and various other prior-art references.

The methods and associated apparatus just described exhibit various shortcomings. In the technique described with reference to Figure 2B herein, although movements within the curing cement bed are further restricted, the point of substantial stability remains at the distal tip of the implant, enabling a certain level of proximal misalignment to continue, as no true proximal

stabilization is provided. Worse, perhaps, is that since the centering rod and bore through the specialized component are both circular, the final implant is still subject to up-and-down and/or rotational variation, resulting in potential misalignment upon fixation.

With respect to the techniques wherein cement is injected after installation, although the implant may be stabilized both proximally and distally as the cement is injected, as with the device of the '085 patent, a specially designed implant including the injector ports must be utilized, resulting in a specialized unit demanding significantly higher cost. Furthermore, regardless of the existing system utilized, attention to the pressure of the cement during injection and curing has not been adequately addressed. Although, for example, the system described in the '163 patent referenced above utilizes various components to maintain pressurization, numerous sophisticated articles are required, including a high pressure nitrogen gas source, disposable cylinder and various associated valves and tubing which may be difficult to assemble, require skilled operators, or create expensive waste and maintenance problems.

The present invention improves upon the prior art by providing a simplified apparatus and associated installation methods whereby an implant may be oriented both proximally and distally prior to the injection of cement, while, at the same time, providing means for guarding against rotational and up/down movement of the implant as well during such injection and subsequent curing. In addition, configurations according to the invention provide a simple means for expelling over-

pressurized cement, thereby yielding a simple, but satisfactory indication that sufficient cement has been injected to an acceptable level. Although, in one embodiment, the invention makes advantageous use of a longitudinal bore through the implant, in another embodiment, all of the above improvements and advantages are realized in conjunction with standard, currently available prostheses, thus resulting in an approach which is both straightforward and economical.

Figure 3 is an oblique drawing of an arrangement according to this invention depicting various independent embodiments. Overall, an implant 310 is shown inserted into a prepared cavity 312, in this case the implant 310 being a femoral hip prosthesis and the cavity 312 being the intramedullary canal, though, as will be apparent to those of skill in the art of orthopaedics, the general principles disclosed herein are not restricted to this application, and may be used in other joint situations, including the knee, shoulder and other situations. Certain features of the femur are shown such as the greater trochanter 313 and lesser trochanter 315, and it is assumed that a resection not visible in this figure has been performed on at least a portion of the proximal end of the femur along with reaming and other preparation of the medullary canal itself to accept the implant 310.

Broadly, according to the invention, an apertured proximal sealing cap is installed over the resection portion of the femoral shaft, the prosthesis 310 is inserted through the proximal opening 320 of the seal, and cement is injected through an injection port 322. In a preferred embodiment, this proximal seal includes a

horseshoe-shaped collar 330 having one or more means such as thumb screws 332 for releasably securing the collar 330 over the bone, and a preferably pliable gasket 334 made from rubber or other suitable polymeric materials through which the aperture 320 is formed. Also located on and through this gasket 334 is a flap valve 336 wherein the material forming the gasket 334 is adjusted to flap open or rupture at a predetermined pressure level, preferably on the order of 25 mm of mercury, which has shown to be advantageous for such orthopaedic purposes. Preferably, this flap valve 336 is formed either by scoring the material of the gasket 334 in a manner conducive to such rupture, or, alternatively, the material may be thinned in this area to break under load.

The embodiment of the proximal seal just described is that preferred for use in conjunction with standard, commercially available implants. That is, the aperture 320 formed in the gasket 334 may take the form of a slit, an oval, or another shape appropriate to the stem of the implant, enabling the device to be inserted therethrough and retained in place by the surrounding material of the gasket 334 against the stem, either through friction or high-tolerance. Alternatively, then, if a more precise geometry of the stem at the point where it emerges through the proximal seal is known, the material 334 may be of a more rigid composition, and may, in fact, be integrally formed to the collar 330, in which case the injection port 322 and valve 336 may be more elaborate and substantial. For example, if the area 334 is metal, the port 322 may be threaded for a more solid connection to commercially available injector nozzles, and the valve 336

may take advantage of more sophisticated pressure-release techniques available in the art, including adjustability for a particular pressure or range of pressures.

Whether the implant is of a standard configuration or specialized for use in conjunction with the invention, a distal spacer 340 is preferably utilized for distal centering. A longitudinal rod 342 may optionally be added to, or installed on the plug 340, requiring a specialized implant having a longitudinal bore 344 akin to that described in the '085 patent referred to above, the exception being that, according to this invention, the implant 310 would be monorailed onto the optional rod 342 prior to the injection of cement into the cavity formed between the walls of the implant and the prepared medullary canal. Thus, as discussed above, the present invention may either be used with a specially prepared implant having this longitudinal bore and/or convenient wall geometries or, alternatively, and unlike the prior art, a standard prosthesis may be used.

In the event that the prosthesis includes an arrangement to assist in installation or removal such as ring 350, the alternative proximal stabilization configuration of Figure 4 may be used. To further assist in proximal securement, a multiple degree-of-freedom clamp arrangement illustrated generally at 404 may be attached to a proximal cover 406 secured to femoral end or attached to a portion of available bone material by whatever means. In the embodiment shown, a first rod 408 securely affixed to the member 406 at point 409, onto which there is disposed a slidable collar 412 which may be locked into position with a suitable device such as thumb screw 414. A second

rod 420 and collar 422 contains two thumb screws, one to lock the collar 422 in position along rod 420, and a different thumb screw 430 for positive engagement with the prosthesis proper. It will be understood to those of skill that various other approaches may be utilized in accordance with the general principle contained herein to grasp and hold any portion or aperture of a standard implant without requiring its modification.

Figure 4 also shows an alternative distal plug according to the invention which may be used in combination with any of the embodiments previously described. With such an inventive plug, it is first seated distally at an appropriate distance within the intermedullary canal, and includes a plurality of deformable upwardly oriented leaf springs 490. Accordingly, with the plug 480 installed in place as shown, an even more generalized type of implant, and not requiring an actual, solid connection to such a distal spacer, may be inserted down and into the medullary canal and held in place while resisting distal side-to-side motion as the distal tip of the implant is retained within these leaf springs 490. This also allows adjustments in a longitudinal direction enabling fine tuning at the effective length of the implant. Note in Figure 4 that the aperture through which the implant is inserted is quite a bit larger than that shown in Figure 4 and, in fact, does not include a seal per se. This is due to the fact that, in accordance with this embodiment, cement may, in fact, be injected prior to or after the implant is held in place both proximally and distally. Indeed, according to this particular embodiment, a standard distal plug may be used in conjunction with the mechanism shown generally at 404

even without a cap or collar as shown. For example, this mechanism 404 may simply attach to an existing bone surface or structure instead of the point 409, thereby holding the implant in place proximally and distally while preventing motion in all dimensions as the cement cures, regardless of when it was injected. In accordance with an alternative methodology, the proximal and distal stabilizers may be used in conjunction with a trial then, upon achieving a desired orientation, a single manual fastener may be loosened, and the actual implant installed in the exact configuration of the trial to guarantee proper positioning.

Figure 5 illustrates an alternative embodiment of the invention, seen generally at 502 from an oblique perspective. In this case, a prosthesis 504, which may have a threaded bore along an axis 508 to receive a threaded fastener such as a bolt 506, is physically coupled to a first structural element 520 which slidably engages with a collar 530, and which may be tightened in place with a manual fastener such as thumb screw 532. Other types of fasteners, including those requiring tools such as set screws, may alternatively be utilized for this purpose. In this embodiment, the prosthesis 504 may be rotated about the axis 508 with the bolt 506 in a slightly loosened condition, and then tightened when a desired angular rotation is achieved. A score mark 522 may be used in conjunction with score marks 524 to provide an indication of this desired angular rotation for future reference. Preferably, score marks are provided on the underside of member 520 as well in the vicinity of the attachment to the prosthesis, to assist in maintaining the desired rotational configuration once the bolt 506 is tightened. Prosthetic

devices having a threaded bore along axis 508 are available from the Zimmer Company, though in the event that such a feature is not provided for, connection may be made to the prosthetic element itself as disclosed elsewhere herein, rendering this threaded bore convenient but not necessary to the invention.

Preferably in this embodiment a set of score marks 526 are also provided on the member 520, such that with the member 520 being moved back and forth to adjust the lateral or transverse positioning of the implant, the fastener 532 may be used to lock the configuration in place, with the marks 526 being used to maintain a visual indication of the desired lateral configuration. Attached to collar 530 is a downwardly extending member 540, which is received by a collar 544 having a manual adjustment device 546. The member 540 may also include markings 542, such that, as the element 540 is moved up and down to adjust for the axial length of the prosthesis, fastener 546 may be locked with the score marks 542 providing a visual indication.

The collar 544 is attached to a clamp 550, which is rigidly attached to the outer surface of the femur through manual fasteners 552 and 554. As a further optional convenience, the collar 544 may be rotationally variable, and locked into place along with member 540 with manual fastener 546, with optional score marks 560 being used as a visual indication of this configuration, if so desired.

Although the various embodiments of this invention may be used to properly position a trial implant prior to the positioning of a final prosthetic element, it

should be apparent that in all cases, the device such as 504 in Figure 5 is assumed to be the final implant itself, thereby eliminating the need for a trial. Particularly if the various positioning elements of the invention are sufficiently low in profile, the entire assembly, including those shown in the figures, joint reduction may be carried out, with the various fasteners being adjustably and rigidly clamped, with the final implant positioned in place and rigidly connected thereto. Following this procedure, the properly positioned implant may be removed from its reduced configuration and cemented. According to the invention, depending upon the circumstances, the prosthesis may be cemented *in situ*, with the various positioning members according to the invention remaining locked in place, or, alternatively, one or more of the fasteners may be loosened, with the implant and, perhaps, other fasteners attached thereto, removed and repositioned once cement has been injected into the intramedullary canal.

For example, referring to the embodiment of Figure 5, fastener 546 may be slightly loosened, with the prosthesis 504 and members 520 and 540 rigidly attached thereto being temporarily removed, the cavity filled with cement, and the prosthesis with members 520 and 540 reinserted, with member 540 being reinstalled into collar 544, utilizing the score marks 542 to ensure that fixation will take place at a proper and desired orientation upon re-tightening of the fastener 546. It will also be apparent that in the embodiment of Figure 5 and others disclosed herein, that if the assembly attached to the femur and to the prosthetic element through using one or more structural elements according to the invention is

sufficiently rigid, positioning of the final implant may be stabilized in three dimensions (for example, rotationally, transversely, and axially -- i.e., with respect to the coronal, sagittal and transverse planes).

Having thus described my invention, what is claimed is:

1. Apparatus for positioning a prosthetic element relative to a bone to achieve a desired orientation, comprising:

a device which rigidly and removably attaches to the bone; and

at least one structural element to rigidly couple the device attached to the bone to the prosthetic element, the structural element including one or more fasteners which may be loosened to adjust the orientation of the prosthetic element relative to the bone, then tightened once the desired orientation is achieved.

2. The apparatus of claim 1, including a plurality of structural elements facilitating a multidimensional desired orientation.

3. The apparatus of claim 1, wherein the bone is a femur and the prosthetic element is an intramedullary implant.

4. The apparatus of claim 3, including a plurality of structural elements enabling the prosthetic element to be adjusted rotationally, transversely and axially in order to achieve the desired orientation.

5. The apparatus of claim 3, further including a device to distally center the implant within the intramedullary canal of the femur.

6. The apparatus of claim 1, wherein the device which rigidly and removably attaches to the bone is a

collar which surrounds at least a portion of the bone and includes one or more fasteners which engage with an outer surface of the bone to hold the collar in place.

7. The apparatus of claim 1, including a first structural element having one end attached to the device and a second structural element having one end attached to the prosthetic element, the other ends of both structural elements being adjustably and lockingly connected to one another.

8. Apparatus for maintaining the proper positioning of a femoral implant having proximal and distal ends within a intramedullary canal during cementation, comprising:

a collar which removably surrounds at least a portion of the femur, including means facilitating rigid attachment thereto;

at least one structural element to rigidly couple the collar to the femoral implant, the structural element including one or more fasteners which may be loosened to adjust the orientation of the prosthetic element relative to the bone, then tightened once the desired orientation is achieved.

9. The apparatus of claim 8, including a first structural element having one end attached to the collar and a second structural element having one end attached to the implant, the other ends of both structural elements being adjustably and lockingly connected to one another.

10. The apparatus of claim 8, including a plurality of structural elements enabling the implant to be adjusted rotationally, laterally, and in terms of length in order to achieve the desired orientation.

11. The apparatus of claim 8, wherein the collar is removably securable to the end of the femur, and further includes an apertured cap through which the implant is inserted and held in place.

12. The apparatus of claim 11, wherein the apertured cap further includes a first port associated with cement injection and a second port associated with cement over-pressurization.

13. The apparatus of claim 8, further including an intramedullary plug engageable with the distal end of the implant.

14. The apparatus of claim 13, wherein the plug includes a plurality of upwardly oriented leaf springs configured to engage with the distal end of the implant.

15. The apparatus of claim 13, wherein the plug includes a vertically oriented rod and the implant includes a longitudinal bore to receive the rod.

16. The apparatus of claim 11, wherein the aperture of the cap has a predetermined shape geometrically matched to an outer portion of the implant extending therethrough.

17. The apparatus of claim 11, wherein the cap is comprised of a pliable material at least in the vicinity of the aperture, enabling the implant to be inserted therethrough and frictionally retained.

18. The method of positioning a prosthetic element relative to a bone so as to achieve a desired orientation, comprising the steps of:

attaching a base unit to the bone, including an adjustable, lockable structural assembly having an end adapted for attachment to the prosthetic element;

adjusting the orientation of the prosthetic element relative to the bone with the structural assembly attached thereto; and

locking the prosthetic element into position once achieving the desired orientation.

19. The method of claim 18, wherein the bone is a femur and the prosthetic element is an intramedullary implant.

20. The method of claim 18, wherein the steps of adjusting the orientation of the prosthetic element and locking the prosthetic element into position are performed as part of a joint reduction.

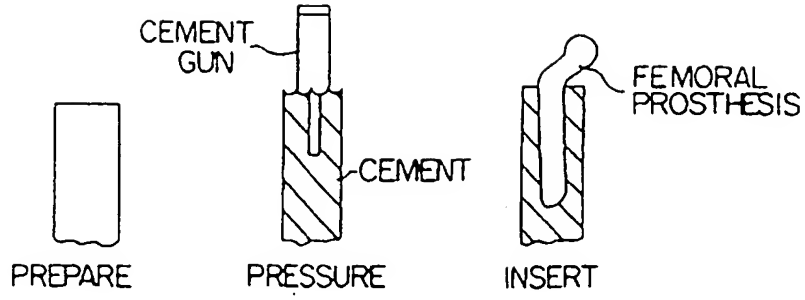


FIG. 1A PRIOR ART

FIG. 1B PRIOR ART

FIG. 1C PRIOR ART

(PRIOR ART)

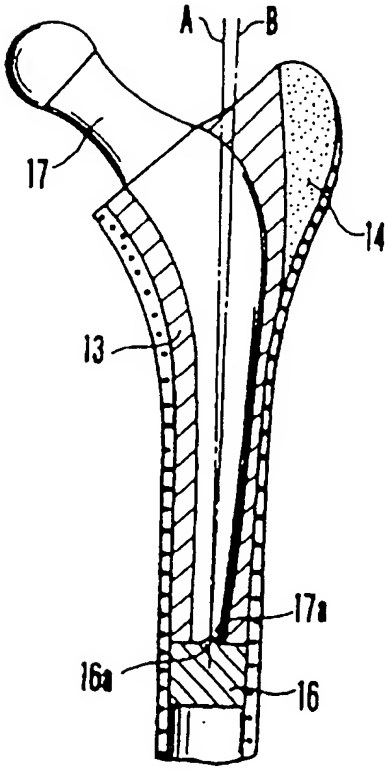


FIG-2A

(PRIOR ART)

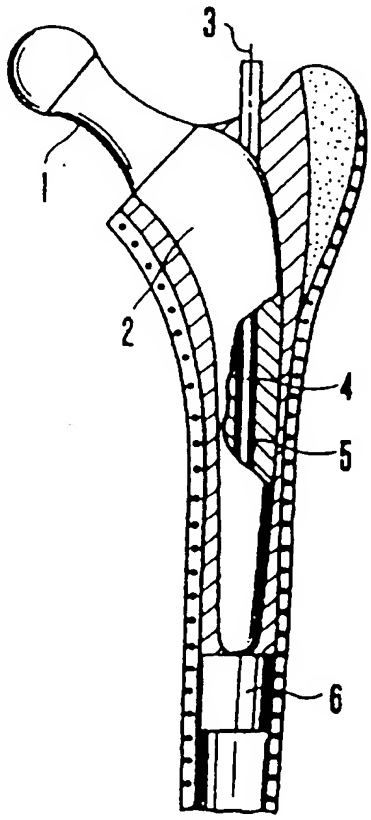
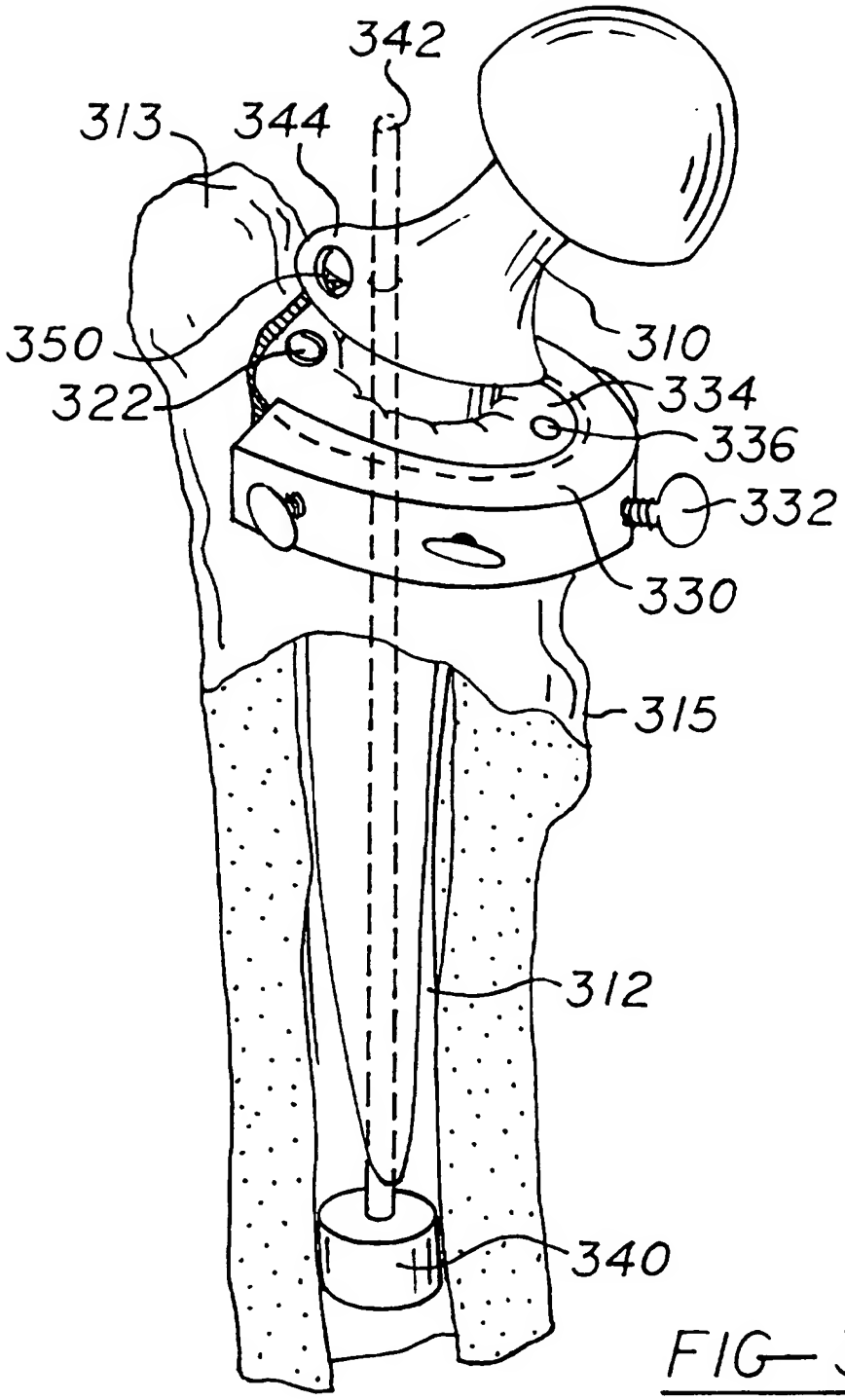


FIG-2B



FIG—3

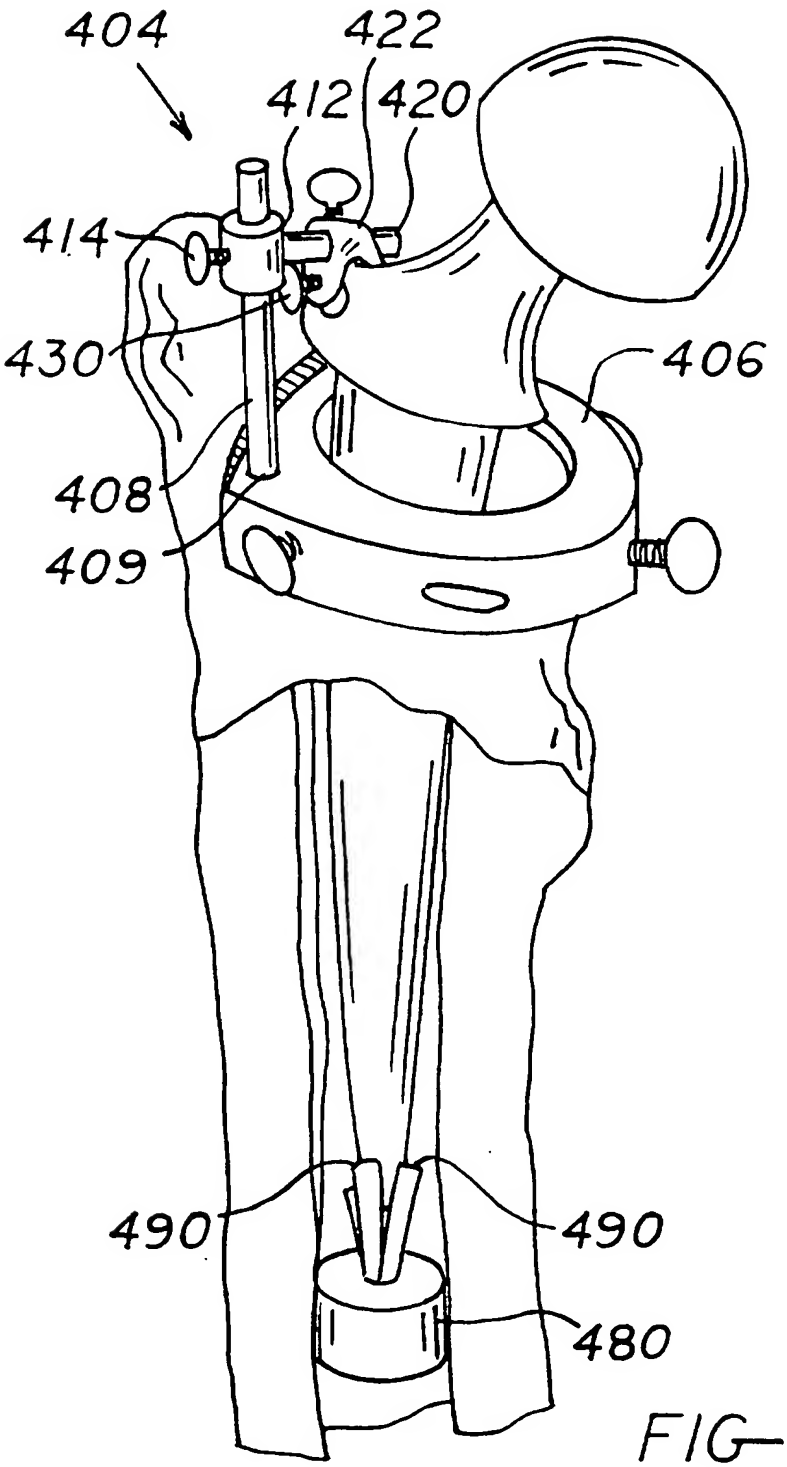
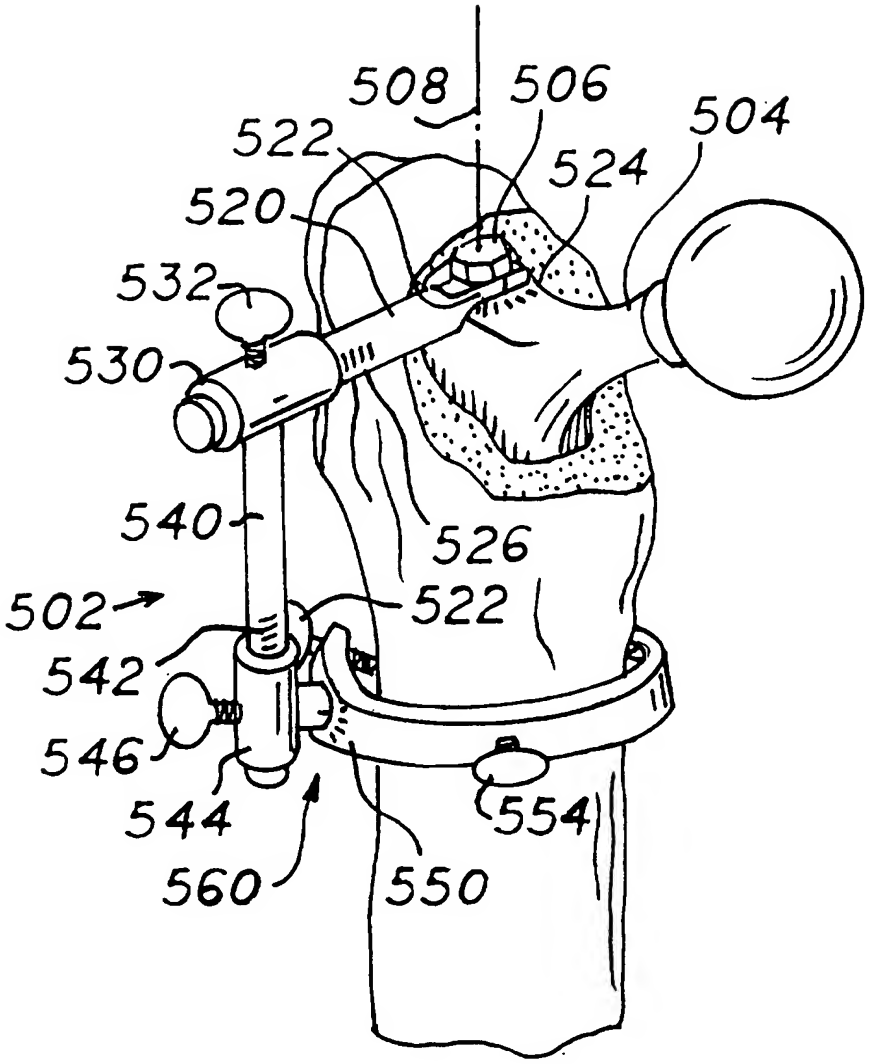


FIG-4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FIG— 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/01754

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61F 2/32, 5/04
US CL :606/92; 623/23
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/92-95; 623/16, 23

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,047,061 A (BROWN) 10 September 1991, entire document.	1-4, 6-12, 16, 17 --- 5, 13-15
Y	US 4,404,692 A (EFTEKHAR) 20 September 1983, Figs. 7, 10-12 and 14-16.	5, 13-15
X	US 4,357,716 A (BROWN) 09 November 1982, entire document.	18-20
Y	US 5,078,746 A (GARNER) 07 January 1992, entire document.	15

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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